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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,358	04/15/2004	Ahmad K. Hilaly	1533.6040002/PAJ/NJL	6313

26111 7590 02/23/2005

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EXAMINER	
WEIER, ANTHONY J	

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,358	HILALY ET AL.	
	Examiner	Art Unit	
	Anthony Weier	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 35-68 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 35-68 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Rejections Under 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 35-68 are rejected under 35 U.S.C. 102(b) as being **anticipated** by Gugger et al (e.g. col. 6, first full paragraph) or JP 5170756 (abstract)

Gugger et al discloses a high purity isoflavone enriched fraction from soy molasses as a source wherein same is, for example, processed and dried into a crystal form (e.g. 90%; see col. 5, line 59 - col. 6, line 16).

JP 5170756 discloses a high purity isoflavone enriched fraction wherein same is processed into a dried, inherently, crystal form (e.g. 90% purity).

It should be noted that the instant claims are essentially product-by-process claims and that the process limitations recited therein have all been considered. However, "though product –by –process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process." See In re Thorpe, 227 USPQ 964.

3. Claims 35 and 39-51 are rejected under 35 U.S.C. 102(b) as being **anticipated** by JP 07070170 or Zilliken.

JP 07070170 discloses a high purity isoflavone enriched fraction wherein same is processed to a purity of at least 99% (see Examples).

Zilliken discloses an isoflavone enriched fraction that is "essentially pure" (col. 6, line 28). Absent a showing otherwise, "essentially pure", as set forth in Zilliken, is reasonably considered to fall within the range of 70-100% or greater than 90% as set forth in the instant claims 35 and 39.

It should be noted that the instant claims are essentially product-by-process claims and that the process limitations recited therein have all been considered. However, "though product –by –process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is

unpatentable even though the prior art product was made by a different process." See In re Thorpe, 227 USPQ 964.

4. Claims 35-37 and 39-51 are rejected under 35 U.S.C. 102(b) as being **anticipated** by JP 7-173148.

JP 7-173148 discloses a high purity isoflavone enriched fraction wherein same is processed to a purity of at least 95%.

It should be noted that the instant claims are essentially product-by-process claims and that the process limitations recited therein have all been considered. However, "though product –by –process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process." See In re Thorpe, 227 USPQ 964.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35-37 and 39-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Fujikawa et al.

Fujikawa et al discloses a high purity isoflavone enriched fraction wherein same is, for example, processed and dried into a crystal form (e.g. 95%; see Example 1; col. 7, lines 5-9).

It should be noted that the instant claims are essentially product-by-process claims and that the process limitations recited therein have all been considered. However, "though product –by –process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-

process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process." See In re Thorpe, 227 USPQ 964.

Rejections Under 35 U.S.C. 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 36-38 **are** rejected under 35 U.S.C. 103(a) as being unpatentable either one of Zilliken (as applied in paragraph 3) and JP 07070170 (as applied in paragraph 3.

None of said references disclose attaining a purity of 90% or a purity within the other ranges of instant claims 36 and 37. However, attaining a certain degree less purity would have been well within the purview of one having ordinary skill in the art and, absent a showing of unexpected results, it would have been obvious to one having ordinary skill in the art at the time of the invention to have arrived at such amounts through routine experimental optimization as a matter of preference depending on cost involved, time, etc.

7. Claim 38 **is** rejected under 35 U.S.C. 103(a) as being unpatentable over either one of JP 7-173148 (as applied in paragraph 4) or Fujikawa et al.

JP 7-173148 and Fujikawa et al do not disclose attaining a purity of 90%, specifically. However, attaining a certain degree less purity would have been well within the purview of one having ordinary skill in the art and, absent a showing of unexpected results, it would have been obvious to one having ordinary skill in the art at the time of the invention to have arrived at such amounts through routine experimental optimization as a matter of preference depending on cost involved, time, etc.

8. Claims 52-55, 57-68 **are** rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Zilliken (as applied in paragraph 3), JP 07070170 (as applied in paragraph 3), and JP 7-173148 (as applied in paragraph 4) taken together with Charihorsky.

The claims further call for said product having been dried and produced in the form of crystals. Zilliken, JP 7-173148, and JP 07070170 are silent concerning same. However, Chairhorsky teaches a process of producing isoflavone enriched material through processing of soybean material through chromatography treating wherein the produced isoflavone enriched material is evaporated, thus inherently producing crystals, and wherein said material is then dried (col. 5, liens 57-62). It would have been obvious to one having ordinary skill in the art at the time of the invention to have provided a product form that was evaporated or dried and to such extent as to form crystals. as a further means of isolating the isoflavone product and purifying same from other components used during processing. It would have been further obvious to have employed such drying to provide a form of the product which would have less weight (and lower shipping cost)and more likely to be preserved for a longer time (see cols. 7 and 8 of Charihorsky).

As discussed above none of Zilliken, JP 7-173148, and JP 07070170 disclose attaining a purity of 90% as also called for in claim 60. However, attaining a certain degree less purity would have been well within the purview of one having ordinary skill in the art and, absent a showing of unexpected results, it would have been obvious to one having ordinary skill in the art at the time of the invention to have arrived at such amounts through routine experimental optimization as a matter of preference depending on cost involved, time, etc.

Answer to Applicant's Arguments

9. Applicants argue that Gugger et al does not disclose an isoflavone enriched fraction that is greater than 70% and is obtained by a process comprising two chromatography steps. It should be noted that the instant claims are directed to a product invention and not the process of producing same. Even though the process of Gugger et al may differ, it is asserted that the same product would be formed. It should be further noted that Gugger et al discloses an isoflavone fraction that is 80-90% pure (e.g. first full paragraph of col. 6).

The **Declaration** filed on **11/18/04** under 37 CFR 1.131 is sufficient to overcome the **JP 2002-80474 and JP 2002-3487** references.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

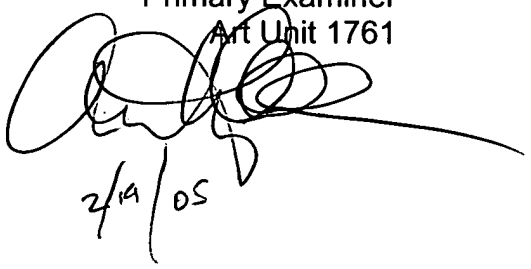
A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Weier whose telephone number is 571-272-1409. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached at 571-272-1398. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3602 for all communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1700.

Anthony Weier
Primary Examiner
Art Unit 1761



Anthony Weier
February 14, 2005